



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/522,087

07/26/2005

Steffen Goletz

10913.0002-00000

7596

22852

7590

10/06/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP

901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/522,087</p>	<p><b>Applicant(s)</b> GOLETZ ET AL.</p>	
	<p><b>Examiner</b> HONG SANG</p>	<p><b>Art Unit</b> 1643</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 24 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): None.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 2, 9 and 10.

Claim(s) withdrawn from consideration: 11.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

/Hong Sang/  
Art Unit 1643

/Christopher H Yaen/  
Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because: applicant's arguments are not deemed persuasive to overcome the rejection of record. The response states Snijdwint does not teach that the MUC1 molecule purified from cell culture supernatant are able to generate an immune response in humans, the antibody used in Snijdwint does not have the features recited in the claims, and other references do not remedy the defects of Snijdwint and Ryuko. Applicant's arguments have been carefully considered but are not persuasive. Applicants are reminded that it is obvious from the teachings of the cited references to modify the method of Snijdwint et al. to use the monoclonal antibodies disclosed by Ryuko to isolate MUC1 antigens from a cell lysate of a breast cancer cell line. The antibodies of Ryuko et al., such as A76-A/C7 and VU-2G7 have the features recited in the claims. The MUC1 antigens isolated by the antibodies of Ryuko et al. including A76-A/C7 would be able to generate an immune response in humans. One would have been motivated to do so because Ryuko discloses that his antibodies react with all the MUC-1 expressing cancer cell lines, and glycosylated MUC1 peptides may be better agents for immunotherapy than non-glycosylated ones (see page 208, column 2).

#### Withdrawal of claim 11

Applicant's traversal of the withdrawal of claim 11 as non-elected invention is acknowledged. The traversal is on the ground(s) that claim 11 was grouped with claims 1-3, 7, 9 and 10 in the restriction requirement mailed 2/4/2008. This is not persuasive because the original claim 11 is to use of a MUC1 molecule for producing a pharmaceutical composition for the treatment of tumors. As such original claim 11 is for producing a pharmaceutical composition. The amended claim is a method of treating tumors using a MUC1 molecule. A method of treating tumors using a MUC1 molecule, and a method of production or identification of a MUC1 molecule using an antibody are distinct because they comprise different steps and use different products. Different method steps and products would require different searches. Moreover, the inventions of these two methods have a separate status in the art because of their different classifications. As such, searching these inventions together would impose serious search burden. Because of these reasons, the withdrawal of claim 11 is deemed proper.

#### Priority

Applicant's submission of an application data sheet that indicates the filing date of European Patent Application No. 02016440.6 is acknowledged.

#### Drawings

Applicant's submission of replacement drawings for Figure 5D(2) and Figure 5D(3) is acknowledged.

#### Objections Withdrawn

The objection to claim 9 because the claim contains non-elected inventions is withdrawn in view of applicant's amendment to the claim.

#### Objections Maintained

The objection to claims 1, 2, 9 and 10 for reciting "wherein the mixture of MUC1 molecules is a cell line that express and/or secretes tumor associated MUC1 molecule" is maintained. The amended claims read on the mixture of MUC1 molecules is expressed and/or secreted by a cell lysate of the cell line. Unlike live cells, a cell lysate does not express and/or secrete MUC1 molecules. Cell lysate is used to obtain or isolate MUC1 molecules.